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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,982	02/27/2002	Arjan Scheepens	37522-10006	8750

66936 7590 01/25/2007

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EXAMINER	
GUCKER, STEPHEN	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/786,982	SCHEEPENS ET AL.	
	Examiner	Art Unit	
	Stephen Gucker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-34,49,50 and 56-59* is/are pending in the application.

4a) Of the above claim(s) *57 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-34,49,50,56 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.

3. Newly amended or submitted claims 57 and 59 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Amended claim 57 is not drawn to the elected species of secondary neuroprotective agent GPE, but to IGF-1. Newly submitted claim 59 is not drawn to the elected species of stroke, but to other disorders

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 57 and 59 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claim 56 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for growth hormone (GH), does not reasonably provide enablement for an analog thereof or a functionally equivalent ligand for reasons of record and the following. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teaches GH but does not provide any working examples of the use of non-GH products that are neuroprotective. Furthermore, the claims are so broad as to encompass any product that possesses the *functionality* of GH without any limitation as to that product's *structure* or chemical composition as long as it possessed the biological properties of GH (*In re Fisher*, 166 USPQ 18). Because GH is a polypeptide, the structure or chemical composition of any product that would be encompassed by the mere functionality requirement of the instant claims is quite unpredictable, and to enable the full reasonable scope of the claims would require undue, painstaking experimentation (see Rudinger, page 6), even for those of highest skill in the art (i.e. physicians and scientists, again consult Rudinger). The instant disclosure does not provide sufficient working examples or guidance commensurate with the very broad scope of the claimed compositions and methods that would encompass unenvisioned functional embodiments of all manner of products, be they specifically undescribed endogenous polypeptides, synthetic GH-like polypeptides with additions, substitutions, or deletions to the GH amino acid sequence, carbohydrates, lipids, nucleic acids, smaller organic molecules, etc.

Applicant's amendment filed 10/20/06 obviated the grounds of this rejection for claim 30, but not for claim 56.

5. Claim 56 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record and the following. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

time the application was filed, had possession of the claimed invention. No adequate description is given for the broad genus of GH analogs and functionally equivalent ligands because these analogs and ligands are only functionally described, and the teachings of the specification do not reveal a generic underlying structure, composition, or motif by which the skilled artisan would recognize that the inventors had possession of the entire broad genus.

Applicant's amendment filed 10/20/06 obviated the grounds of this rejection for claim 30, but not for claim 56.

6. Claims 30-34, 49-50 and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support for the claim limitation "protecting or rescuing neurons destined to degenerate or die as a result of hypoxia or ischemia". The specification does teach protecting or rescuing neurons destined to degenerate or die as a result of a prior neuronal insult, which is defined as trauma (injuries), degenerative diseases and disorders, motor diseases and disorders, demyelinating diseases and disorders, neurological syndromes, eye diseases and sleep disorders (specification, page 3, lines 10-18). Hypoxia and ischemia are not listed. This is a new matter rejection.

7. Claims 30, 32-33, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Golab et al. ("Golab") in light of Burman and/or Nyberg (see last office

action) for reasons of record and the following. Golab describes, beginning with the last paragraph on page 234, the treatment of stroke patients with STH (somatotropin or growth hormone) composition. The case studies on page 235 indicate that a 54 year-old woman who initially suffered paralysis of the extremities and face recovered functional movement for all but the left corner of her mouth after being administered growth hormone. The other case study indicates that a 58 year-old woman also recovered functional use of the right side of her body after being administered growth hormone. The first woman was diagnosed as having suffered a cerebral embolism and the second woman was diagnosed as suffering a cerebral hemorrhage and they were treated with growth hormone over a period lasting up to six or ten days. The single reference Golab is being understood in terms of the undisclosed but inherent properties of growth hormone in light of the teachings of Burman and/or Nyberg that growth hormone administered to the periphery of the human body has the inherent property of being able to pass into the cerebrospinal fluid of the human body (see Fig. 1-Fig. 2 and first paragraph of discussion on page 322), thereby coming into contact with the brain, and by so doing induce a neuroprotective effect in a brain of a patient as recited by the instant claims and as observed in the recovery of the stroke patients administered growth hormone as described by Golab (see *Ex parte Novitski*, 26 USPQ2d, 1389).

The Examiner was unable to obtain an official written translation from the Polish for the Golab reference before a first office action on the merits for the case was due. A translation has been requested for the case file and will be forwarded to Applicant to review in a future office action in response to Applicant's response to this office action.

Applicant's arguments filed 10/20/06 have been fully considered but they are not persuasive. Applicant merely makes unsupported assertions that Golab is not enabled or does not meet the limitations of the claims without providing any sound scientific evidence or reasoning. Golab teaches a method of administering the same substance in the same manner to treat the same condition as the instant invention. If Golab does not anticipate the claims, then the instant invention must logically not be enabled! (see Ex parte Novitski, 26 USPQ2d, 1389). A translation of Golab is provided with this Office Action.

8. Claims 30-33, 49-50, and 58 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,187,906 B1 in view of Golab for reasons of record and the following. The patented claims teach methods using GPE as a neuroprotective agent for dopaminergic neurons. The patented claims do not teach methods using GH as a neuroprotective agent. Golab does teach methods using GH as a neuroprotective agent in stroke as set forth in ¶7 above. It would have been obvious for one of ordinary skill in the art at the time of the invention to combine the two methods because each method is intended to produce the same result of neuroprotection and the ordinary artisan would find the suggestion *prima facie* obvious that a combination of two different methods intended to produce the same therapeutic result would be additive, thereby providing the motivation of neurologically improved patient care, as all neurons are subject to neuronal death from stroke, including dopaminergic neurons, and thus there is a reasonable expectation of success as demonstrated by the enabled patented claims.

Applicant's arguments filed 10/20/06 have been fully considered but they are not persuasive because Applicant argues the references separately and not in combination. It is Golab that the Examiner is relying on to teach the GH administration method, and the patented claims for the GPE administration, as explained in the statement of motivation. Furthermore, Applicant merely makes unsupported assertions that Golab is not enabled or does not meet the limitations of the claims without providing any sound scientific evidence or reasoning. Golab teaches a method of administering the same substance in the same manner to treat the same condition as the instant invention.

9. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US 6,187,906 B1, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claim 50 is directed to an invention not patentably distinct from claims 1-11 of commonly assigned US 6,187,906 B1. Specifically, the patented claims teach methods using GPE as a neuroprotective agent.

10. Claims 30-33, 49-50, 56, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golab in view of Gluckman et al. (US 6,187,906 B1, "Gluckman") for reasons of record and the following. Golab teaches methods using a GH composition as a neuroprotective agent in stroke as set forth in ¶7 above. Golab does not teach a GPE composition or methods of use. Gluckman (effective filing date August 11, 1997) does teach GPE compositions and methods of use (abstract, column 9, line 15 to column 10, line 5). It would have been obvious for one of ordinary skill in the art at the time of the invention to combine the two methods because each method is intended to produce the same result of neuroprotection for stroke (hypoxic-ischemic brain injury) and the ordinary artisan would find the suggestion *prima facie* obvious that a combination of two different methods intended to produce the same therapeutic result would be additive, thereby providing the motivation of neurologically improved patient care, as all neurons are subject to neuronal death from stroke, and there is a reasonable expectation of success as demonstrated by the enabled patented claims.

Applicant's arguments filed 10/20/06 have been fully considered but they are not persuasive because Applicant argues the references separately and not in combination. It is Golab that the Examiner is relying on to teach the GH administration method, and the patented claims for the GPE administration, as explained in the statement of motivation. Furthermore, Applicant merely makes unsupported assertions that Golab is

not enabled or does not meet the limitations of the claims without providing any sound scientific evidence or reasoning. Golab teaches a method of administering the same substance in the same manner to treat the same condition as the instant invention.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached at (571) 272-0867. The fax phone number for this Group is currently (571)-273-8300.

SG

Stephen Gucker

January 22, 2007

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER